

Based on the provisions of the 52<sup>nd</sup> Article of the University of Ljubljana Statutes (Official Gazette of the Republic of Slovenia, , No. 4/2017, 56/17, 56/17, 14/18, 39/18, 57/18, 66/18, 10/19, 22/19, 36/19, 47/19, 82/20, 104/20, 168/20; hereinafter referred to as Statutes UL) the University of Ljubljana Senate at its 36<sup>th</sup> session dated 30 March 2021 adopted the following

**POLICY ON THE MANAGEMENT OF FINANCIAL CONFLICT OF INTEREST IN  
RESEARCH AT THE UNIVERSITY OF LJUBLJANA FUNDED BY THE PUBLIC  
HEALTH SERVICES OF THE UNITED STATES OF AMERICA (PUFNIR UL)**

Article 1

(General provisions)

The University of Ljubljana (UL) has adopted the Rules on Avoidance of Conflict of Interest and Work Outside UL (PINI UL), which define the concepts of financial interest, conflict of interest, persons to whom the provisions of the Rules apply, and conduct regarding the position of individuals who may have a financial conflict of interest (FCOI) or whose position represents an apparent FCOI.

The present Policy serves to supplement the PINI UL with the specific requirements of the Public Health Services (PHS)<sup>1</sup> of the United States of America, which funds the research. These requirements proceed from regulation 42 CFR 50, Subpart F “Promoting objectivity in research”.<sup>2</sup>

Article 2

(Purpose and scope of application)

The purpose of this Policy is to promote objectivity in research and in particular to ensure that the design, conduct, or reporting in **research funded under grant agreements or cooperative agreements with the PHS** will be free from bias resulting from Investigator FCOI.

**Any UL Faculty that applies for, or receives, PHS funding for research** under a grant or cooperative agreement, and any person **that plans to participate in or is already participating in such research, must act in accordance with the stated regulation, which is implemented through this Policy.**

The persons deemed to be involved in applications, implementation, reporting, and other decisions related to PHS research are employees as defined in point 2.1 of PINI UL<sup>3</sup> and also contractual partners in these projects (e.g. sub-contractors, and members of consortiums).

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<sup>1</sup>The PHS includes the following agencies and departments: NIH-National Institutes of Health, Centers for Disease Control and Prevention, Indian Health Service, Food and Drug Administration, Agency for Toxic Substances and Disease Registry, Health Resources and Services Administration, Agency for Healthcare Research and Quality, Substance Abuse and Mental Health Services Administration.

<sup>2</sup> Code of Federal Regulations, Title 42 Public Health, Chapter I. Public Health Service, Subchapter D, Part 50.

<sup>3</sup> UL employees are all teaching and non-teaching, research, and academic staff, including higher education teachers, academic staff and professional service staff who are employed at UL.

Significant financial interest pursuant to this Policy shall also be determined for the family members of persons referred to in the preceding paragraph. Family members are defined in PINI UL.<sup>4</sup>

### Article 3

#### (Definitions)

Proceeding from the definitions of conflict of interest in PINI UL, for the purposes of implementing regulation 42 CFR 50, Subpart F “Promoting objectivity in research”, this Policy additionally defines the following terms:

1. **Significant financial interest** (hereinafter: **SFI**) covers one or more of the stated cases for which it may be reasonably believed that they are associated with the institutional tasks or offices of the employee at UL:
  - If a person has in the twelve months preceding the disclosure received **remuneration from any entity whose shares are publicly traded on world stock exchanges**, and as of the date of disclosure such person holds any equity interest in such entity and the aggregated value of the remuneration and equity interest exceeds **US\$ 5,000**. For the purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship). For the purposes of this definition, equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
  - If a person has in the twelve months preceding the disclosure received **remuneration from any entity whose shares are not publicly traded on world stock exchanges**, and such remuneration has an aggregated value that exceeds **US\$ 5,000**, or if the person holds in such entity any equity interest (e.g. stock, stock option, or other ownership interest).
  - If a person has in the twelve months preceding the disclosure received any income from any entity related to **intellectual property rights and interests** (e.g. patents, copyrights) and the aggregated value of income received exceeded US\$5,000.
  - If a person has in the twelve months preceding the disclosure received **reimbursed or sponsored travel** (paid for and on behalf of the person and the exact monetary value may not be immediately known) **and such remuneration has an aggregated value that exceeds US\$ 5,000 per sponsor**. The disclosure must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The disclosure requirement does not apply to travel that is reimbursed or sponsored by a United States Federal, state, or local authority, a public or non-profit accredited institution of higher education as defined at 20 U.S.C. 1001(a),<sup>5</sup> an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
2. Significant financial interest **does not include the following cases**:
  - salary, or other remuneration paid by UL to the person, if he/she is currently employed at UL or is in a contractual relationship with UL including intellectual property rights assigned to UL and agreements to share in royalties related to such rights;

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<sup>4</sup> Family members of UL employees are spouses, children, adopted children, parents, adoptive parents, siblings, and persons who share a household with the UL employee or are in an extra-marital relationship or partnership with him/her.

<sup>5</sup> U.S. Code, Title 20: Education, Chapter 28, Subchapter I, Section 1001.

- income from mutual or pension investment funds, provided the person is not directly involved in the management or control of such funds;
  - income from seminars, lectures, or teaching engagements sponsored by a United States Federal, state, or local authority, a public or non-profit accredited institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with institution of higher education;
  - Income from service on advisory committees or review panels for the United States Federal, state, or local authority, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
3. **Financial conflict of interest** (hereinafter: **FCOI**) means a significant financial interest that could directly and significantly affect the design, conduct or reporting of PHS-funded research.
  4. **Senior/key personnel** means the project director or principal investigator (PD/PI) and any other person identified as senior/key personnel by the UL in the grant application, progress report, or any other report submitted to the PHS by the UL.
  5. **UL Faculty in the name of UL**<sup>6</sup>: The University of Ljubljana (UL) is composed of more UL Faculties. Based on the mandate from the UL, UL Faculties carry out the activities in legal transactions acting in the name and on behalf of the UL within the framework of the national program of higher education and the national program of research and development for which funds are provided by the Republic of Slovenia, or when funds are acquired from European and other international collaborations and projects financed from public funds.

#### Article 4

##### (Disclosure of significant financial interests)

All UL employees that plan to participate in research funded by the PHS must disclose to the dean of the UL Faculty their SFI for themselves and for their family members, at the latest upon submission of the UL application for funding of research by the PHS. If Investigator's financial disclosure is already on UL Faculty in the name of UL file, investigator only needs to report any change to the SFI data from what was previously disclosed to UL.

Any SFI must also be disclosed by all those who in the course of a research project funded by the PHS newly join such research project.

Anyone who participates in PHS-funded research must provide updated disclosure of a SFI within 30 days of identifying or acquiring the new SFI (e.g. through purchase, marriage or inheritance).

Irrespective of the preceding paragraph, each person must at least annually during the course of a project submit an updated SFI disclosure. Such disclosure must include any information that was not disclosed initially, or in a subsequent disclosure of SFI, and updated information concerning any previously disclosed SFI (e.g. the updated value of previously disclosed equity interests).

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<sup>6</sup> As in Articles 8 and 10 of the UL Statute.

## Article 5

If UL Faculty in the name of UL intends to conduct PHS-funded research via a contractual partner (i.e. a subcontractor or consortium member), UL Faculty in the name of UL must obtain a statement from the contractual partner on whether the partner has internal regulations that define a policy of managing a FCOI that complies with regulation 42 CFR 50, Subpart F. In the statement the contractual partner may specify that it will apply these UL Policy. In this case, by the time an application for PHS funding is submitted, the contractual partner must submit disclosure of any SFI to the dean of the UL Faculty at which the investigator is employed.

Upon approval of funding for the research, the agreement between UL and contractual partner must include the following provisions:

- specifying whether the contractual partner will be subject to the provisions of this Policy and in what extent and manner, or whether the contractual partner has its own internal regulations that serve to implement regulation 42 CFR 50, Subpart F and
- establishing time period(s) for the SFI disclosures or FCOI reports for the investigators of contractual partners that will be sufficient to enable the UL to comply timely with its review, management, and reporting obligations to PHS.

If the contractual partner has its own internal regulation that implements regulation 42 CFR 50, Subpart F, it shall itself assess the existence of a FCOI and report on any identified FCOI and measures to manage the FCOI to UL within 45 days of identifying the FCOI to allow UL to report the FCOI to the PHS Awarding Component within the 60-day required reporting period.

## Article 6

(Reporting on the existence of significant financial interests and assessment of the existence of financial conflict of interest)

UL employees shall report information on the existence of their SFI (and those of their family members) for which it may be reasonably believed that are related to their institutional responsibilities (teaching, research) to the dean of the UL Faculty, for the institution's determination of a FCOI via the *Form for disclosure of significant financial interests for PHS-funded research*.

The dean of each UL Faculty, at which the investigators involved in a PHS-funded project are employed, is the person responsible for the assessment of the existence of investigators' FCOI.

In the event that the investigator is the dean, the existence of any FCOI and measures to manage such conflicts shall be assessed by the UL Rector.

## Article 7

(Managing financial conflict of interest)

Prior to the expenditure of any funds under a project or during project implementation, and within 60 days of the disclosure of SFI, the person responsible for assessment (dean, rector) shall:

- review all disclosures of SFI from employees participating in the project;
- determine whether any SFI relates to research funded by the PHS;
- determine whether any FCOI exists;
- in the event of an identified FCOI, develop and implement a management plan to manage the FCOI.

The SFI is related to the PHS-funded research when the person responsible for the assessment determines that the investigator's SFI could be affected by the research or is in an entity whose financial interest could be affected by the research. An FCOI is an SFI that could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

The person responsible for assessment may include the employee in the procedure for determining whether the SFI is related to PHS-funded research.

A FCOI is established when the person responsible for assessment reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

#### Article 8

- If the person responsible for assessment determines that the reported SFI is **not** related to PHS-funded research or **represents no financial conflict of interest**, he/she shall send a statement to this effect to the competent office at the UL Rectorate within 60 days of the disclosure of SFI. This statement shall affirm that:
- the employee has completed and signed the *Form for disclosure of significant financial interests for PHS-funded research*;
- the person responsible for assessment has assessed whether any FCOI exists in the PHS-funded research and has determined that no such FCOI exists.

#### Article 9

In the event of determining a FCOI the person responsible for assessment shall within 50 days of determining the FCOI send to the competent office at the UL Rectorate the following:

- a supplemented and signed Form for disclosure of significant financial interests for PHS-funded research;
- a plan of measures to manage the FCOI; and
- in the event that the FCOI is not eliminated, a FCOI Report as a basis for UL reporting to the PHS Awarding Component.

#### Article 10

##### (Retrospective review)

Where a FCOI is not determined and managed in a timely manner because an investigator failed to disclose an SFI, the UL Faculty failed to review and make a determination of FCOI, and when the investigator failed to comply with the management plan, the UL Faculty shall be bound to perform a retrospective review of the work performed by the employee and the progress of the PHS-funded project in order to determine whether PHS-funded research, or portion thereof, conducted during

the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

The UL Faculty must perform a retrospective review within 120 days of such circumstance being determined.

Depending on the nature of the SFI, the UL Faculty may determine that additional interim measures are necessary with regard to the employee's participation in the PHS-funded research project between the date that the FCOI or the employee's noncompliance is determined and the completion of the retrospective review.

The UL Faculty in the name of UL must document the retrospective review. The documentation must contain at least the following information:

- (1) Project number;
- (2) Project title;
- (3) Name of the project director or principal investigator (PD/PI) or contact PD/PI if a multiple PD/PI model is used;
- (4) Name of the employee with the FCOI;
- (5) Name of the entity in connection with which the employee has the FCOI;
- (6) The reasons for the retrospective review;
- (7) Detailed methodology used for the retrospective review (i.e. the methodology of the review process, composition of the group conducting the review, reviewed documents and so forth);
- (8) Findings of the review; and
- (9) Conclusions of the review.

## Article 11

### (Reporting on financial conflict of interest)

UL Faculty shall in the name of UL prepare initial, mitigation or annual FCOI report for any FCOI identified.

The competent office at UL Rectorate shall review these documents and submit FCOI Reports to the PHS Awarding Component via the eRA Commons FCOI Module.

The UL shall report to the PHS all cases of an identified FCOI prior to the expenditure of any funds under a PHS-funded project, if the FCOI has not yet been eliminated.

During the course of the research project the UL shall submit to the PHS Awarding Component a report on all instances of FCOI within 60 days after determination that an FCOI exists.

UL will provide an FCOI report to the PHS Awarding Component consistent with the regulation 42 CFR 50. The FCOI report will include at least the following key elements:

1. Project number;
2. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
3. Name of the Investigator with the Financial Conflict of Interest;
4. Name of the entity with which the Investigator has a Financial Conflict of Interest;
5. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
6. Value of the financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000- \$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
7. A description of how the financial interest relates to the PHS funded research and why the Institution determined that the financial interest conflicts with such research;
8. A description of the key elements of the Institution's management plan, including:
  - o Role and principal duties of the conflicted Investigator in the research project;
  - o Conditions of the management plan;
  - o How the management plan is designed to safeguard objectivity in the research project;
  - o Confirmation of the Investigator's agreement to the management plan;
  - o How the management plan will be monitored to ensure Investigator compliance; and
  - o Other information as needed.

For any FCOI previously reported by the UL to the PHS, the UL shall provide an annual FCOI report that addresses the status of the financial interest and any changes to the management plan. The annual report will be submitted for the duration of the project period (including extensions with or without funds) at the same time as UL is required to submit:

- o the annual Research Performance Progress report (two months prior to the next budget period start date for grants not subject to the Streamlined Noncompeting Award Process (SNAP)<sup>7</sup> or 45 days prior to the next budget period start date of the noncompeting continuation award subject to SNAP), or
- o multi-year funded progress report, if applicable, or
- o at the time of grant extension, if applicable.

The annual FCOI report shall contain an indication whether the FCOI is being managed or it no longer exists. If the FCOI is being managed, the report will provide any changes to the management plan during the course of the research project. If the FCOI no longer exists, the FCOI report will explain why.

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<sup>7</sup> Streamlined Noncompeting Award Process (SNAP) is a procedure regarding modifying annual progress reports, Notices of Assessment, and financial reports.

The UL shall submit an annual FCOI report to the PHS Awarding Component within the deadline and in the manner defined by the PHS Awarding Component.

Based on the results of the retrospective review, if appropriate, the UL Faculty in the name of UL shall update the previously submitted FCOI report, specifying the measures that will be adopted to manage the FCOI in the future.

If bias is not found but new information is discovered following completion of the retrospective review, the UL will notify the PHS with the information.

If bias is found, based on documents provided by the UL Faculty, the UL shall notify the PHS Awarding Component promptly and submit a Mitigation report on adopted measures, including all the key elements documented in the aforementioned retrospective review and a description of the impact of the bias on the research project, and the UL plan of action or actions taken to eliminate or mitigate the-effects of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).

## Article 12

### (Public Accessibility)

Prior to the UL's expenditure of any funds under a PHS funded research project, UL shall ensure public accessibility, via written response within five business days of a request, of information concerning any SFI disclosed to UL that meets the following three criteria:

- The SFI was disclosed and is still held by the senior/key personnel;
- UL determines that the SFI is related to the PHS funded research; and
- UL determines that the SFI is a FCOI.

The information that UL makes available via written response shall include, at a minimum, the following:

1. Investigator's name;
2. Investigator's title and role with respect to the research project;
3. Name of the entity in which the SFI is held;
4. Nature of the SFI; and
5. Approximate dollar value of the SFI (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.



UL will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least of annual basis and within 60 days of the UL's identification of a new FCOI, which should be requested by the requestor.

UL will publish on the publicly accessible website the information on the contact email address where individuals can send in their written request for the information above.

### Article 13

#### (Measures to manage financial conflict of interest)

Where a FCOI is determined, the person responsible for assessment shall decide on the measures taken to manage the conflict.

Examples of the conditions and restrictions that may be imposed to manage a FCOI include but are not limited to:

- Public disclosure of a FCOI (e.g. when presenting or publishing the research, to research personnel working on the study, to the institutional or national ethical review committee, etc.);
- For research projects involving human subjects research, disclosure of a FCOI directly to participants;
- Appointment of an independent supervisor capable of taking measures to protect the design, conduct, or reporting of the research against bias resulting from the FCOI;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g. sale of an equity interest); or
- Severance of relationships that create financial conflicts.

### Article 14

In any case in which the HHS<sup>8</sup> determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a FCOI that was not managed or reported by UL, the UL shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

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<sup>8</sup> US Department of Health and Human Services (HHS).

## Article 15

### (Storage of documentation)

The UL Faculty will store documentation relating to FCOI disclosures of employees, including review documents, the decisions of the person responsible for assessment regarding such disclosures (irrespective of whether a disclosure resulted in the person responsible for assessment determining a FCOI with the PHS-funded research), or documentation of any retrospective review if one was performed, and documentation related to all actions based on the internal rules of UL, **for at least three years from the date the final expenditures report is submitted to the PHS**, or otherwise in special cases so provided by 45 CFR 75.361 <sup>9</sup> (for instance if court proceedings, financial review, or an audit are implemented prior to three years elapsing, documentation must be stored up until the end of such procedures, if documentation is stored by the PHS Awarding Component, the investigator shall not be required to store it for three years, for certain types of documents (e.g. plan of division of costs and accounting calculations of indirect and direct costs) the three-year period begins on the date of submission of these documents to the PHS Awarding Component).

## Article 16

### (Information and training for personnel)

The UL will make this Policy available and up-to-date via publicly accessible Web site.

The UL Faculty shall provide information to each employee who plans to apply for or participate in PHS-funded research regarding the PUFNIR UL rules, regarding the duty of employees to disclose any SFI, and regarding PHS regulation 42 CFR 50, Subpart F.

Each employee who is planning to participate in or is participating in PHS-funded research must become acquainted with the PUFNIR UL rules and sign an employee statement on the Form for disclosure of significant financial interests for PHS-funded research, to the effect that he/she understands and accepts the duty to disclose any SFI in accordance with the procedure defined in this Policy.

Each employee shall be bound to undergo training with regard to the above (on the website of NIH, the National Institute of Health<sup>10</sup>), prior to embarking on research associated with any kind of funding from the PHS, at least once every four years, and immediately upon the onset of any of the following circumstances:

- UL amends the PUFNIR UL or procedures, such that this affects the requirements on investigators;
- an investigator is newly employed at UL or collaborates in some other way with UL; or
- UL determines that an investigator is not acting in compliance with the PUFNIR UL or the FCOI management plan.

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<sup>9</sup> Code of Federal Regulations, Title 45 Public Welfare, Subtitle A, Subchapter A, Part 75, Subpart D, Subjgrp **Record retention and access**, Section 75.361.

<sup>10</sup> NIH, Grants & Funding, accessed August 27, 2020, <https://grants.nih.gov/grants/policy/coi/index.htm>.

## Article 17

### (Appeal)

Investigators who do not agree with the finding of the person responsible for assessment that a FCOI exists or who object to the proposed management plan, may lodge an appeal with the Rector. An appeal will suspend the execution of the proposed plan of measures, but only provided that the expenditure of project funds has not yet started or within the framework of the 60-day deadline up to the submission of the report to the PHS Awarding Component. Otherwise the management plan must be implemented at least on an interim basis.

## Article 18

### (Right of access to documentation)

The UL Rectorate shall have the right to access documentation related to FCOI management at UL Faculties.

## Article 19

### (Breach of obligations)

If an employee fails to disclose a SFI or to report changes to disclosed information, or reports erroneous or misleading information, this shall constitute a breach of research integrity and employment contract obligations, and render the employee liable in accordance with the valid regulations and internal bylaws.

## Article 20

### (Final provision)

This Policy shall enter into force on the day after its adoption and publication on the UL website.

Number: prof. dr. Igor Papič

Date: Chair of the Senate of UL

Rector UL